SHELBY COUNTY HEALTH DEPARTMENT

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April 1, 2019

Ms. Jean Rutledge
Plant Manager
Sterilization Services of Tennessee
2396 Florida Street
Memphis, Tennessee 38109

RE: Air Compliance Inspection

Dear Ms. Rutledge:

Enclosed please find a copy of the report of the Air Compliance Inspection performed at the Sterilization Services of Tennessee facility located at 2396 Florida St. on March 13, 2019.

Please refer to the *Findings and Recommendations* section of this report for information regarding issues of pending compliance that were identified during the inspection.

I wish to thank you for the hospitality shown to the inspector during the inspection. Should you have any questions regarding this report please contact Mr. Mark Landry or me at (901) 222-9582.

Sincerely,

Wasim Khokhar
Major Sources Supervisor
POLLUTION CONTROL SECTION

Enclosure

cc: Source Files - #00477
Branch Correspondence Files
Inspection Book

TN OUT-
00477034

PLANT INSPECTION REPORT

COMPANY: Sterilization Services of Tennessee **FACILITY NUMBER:** 00477

CLASSIFICATION: Synthetic Minor **PERMIT EXPIRATION:** 00477-02P: 03/16/2020

ADDRESS: 2396 Florida Street
Memphis, Tennessee 38109 **PHONE NUMBER:** (901) 947-2217

FACILITY NAICS: 561910

PERSON(S) CONTACTED, TITLE(S): Ms. Jean Rutledge, Plant Manager
Mr. Calvin Spencer

PURPOSE OF INSPECTION: Air Compliance Inspection

COMPLIANCE STATUS: Pending Compliance

PRIOR NOTICE: Yes

DESCRIPTION OF FACILITY OPERATIONS: Industrial sterilizer of medical equipment and supplies

ENVIRONMENTAL CONDITIONS: 65°F, Wind – 22 mph (SSE)

PRODUCTION STATUS: Normal

ENGINEER/INSPECTOR: Mark Landry **DATE:** March 13, 2019

TIME: 9:00 a.m. **DURATION ON SITE:** 0.75 hours

PROCESS AND EQUIPMENT DESCRIPTION

The facility currently consists of three sterilizers (one sterilizer is not working) and one aeration room. At the present time, all three sterilizers are connected to a common acid-water scrubber (Damas packed tower scrubber) with a minimum control efficiency of 99 percent. The sterilization chamber exhaust vents and aeration room vents are routed to the catalytic oxidizer for control (the minimum control efficiency of the oxidizer is required to be 99 percent). Sterilization Room 1 is not operating.

New medical products are transferred from the unloading/storage area and loaded into one of the three sterilizers, which are identified as 0101, 0102, and 0103. Ethylene oxide gas is used as the sterilant. The sterilizing cycle includes the following stages: 1) exposure of medical products to sterilant under pressure; 2) sterilant removal, including nitrogen washes and air washes; 3) unloading of sterilized products; and 4) aeration to facilitate off-gassing of ethylene oxide retained in the sterilized products. A computerized system is used to monitor and control the process parameters like pressure, temperature, EtO concentration, and other parameters for the sterilization chambers.

Ethylene oxide emitted from the sterilization chamber vents during the sterilant removal stage, including the vacuum pump discharge during nitrogen and/or air washes, are routed to the acid-water scrubber for emission control. Emissions from the sterilization chamber exhaust vents (~ 2.5% from the unloading of sterilized products) are routed to the catalytic oxidizer for control. The natural gas fired oxidizer consists of two packed beds filled with catalysts. The oxidizer temperature, flame arrestor temperature, pressure, catalyst inlet and outlet temperatures, and other parameters are monitored.

The acid-water scrubber consists of three separate tanks, (two can be used at any one time, one is used for backup), each equipped with a liquor tank level indicator. When the maximum liquor tank level of 60 inches is reached, the content of the tank is vented to the waste tank. The spent scrubbing liquid is discharged to a holding tank and subsequently treated (e.g., neutralized) prior to being loaded into a tank truck and transferred offsite for reuse in other processes. A prescribed mixture of sulfuric acid and water is added to the scrubber and the operation of the scrubber is resumed.

The product absorbs/adsorbs approximately 2.5% of the EtO sterilant, which is subsequently released in the aeration room. The products typically spend a minimum of 24 hours and a maximum of 72 hours in the aeration room. Emissions from the aeration room vent are routed to the catalytic oxidizer for control.

The source originally had two aeration rooms and the catalytic oxidizer had four catalyst beds. Because of reduced throughput, the source took one of the aeration rooms out of service and removed from service two catalyst beds in the catalytic oxidizer A stack test was conducted on July 16, 2015 to demonstrate compliance with the requirements of 40 CFR Part 63 Subpart O.

Depending on the rate of sterilant removal from a particular chamber, one or more chambers can be vented to the scrubber at one time, i.e., the sterilant removal time may be increased if two chambers are being vented instead of one.

INSPECTION DETAILS/COMMENTS

The intended purpose of this inspection was to determine source compliance and to fulfill USEPA commitments. Prior notice of the inspection was provided.

The inspection began with a discussion of facility operations, followed by a walk-through tour. The facility was in operation at the time of the inspection, including both the catalytic oxidizer and the acid-water scrubber. Ms. Rutledge and Mr. Spencer led the inspector on a tour of the permitted equipment, explaining facility operations in detail and assisting the inspector in identifying various operations. The equipment appeared to be maintained in very good condition. The inspector did not observe any unpermitted equipment in place at the facility, and all of the permitted equipment appeared to be in compliance with the facility's operating permit. At the time of the inspection, the catalytic oxidizer was operating at a temperature of 257°F, with a pressure drop reading across the catalyst bed of 5" H_2O. Similarly, the scrubber appeared to be in good condition and working properly during the inspection (the liquid height on sight glass was reading approximately 55 inches at the time of the inspection). No visible emissions were noted from any of the facility's equipment.

The inspection continued with a review of the facility's recordkeeping for the 2018 calendar year. The inspector reviewed records of facility ethylene oxide throughput, scrubber tank liquid height measurements, strip chart recorder output charts, fuel usage and maintenance performed by the facility. The operations records maintained by the facility are current and are maintained in an orderly, easily-reviewable format. Emissions values were not available on-site during the inspection, but they were provided in a timely manner through correspondence. Emission values reported to the Shelby County Health Department (the Department) were cross-referenced against the numbers contained in the facility's recordkeeping system. Some discrepancies were noted during the facility recordkeeping review (see FINDINGS AND RECOMMENDATIONS section below).

FINDINGS AND RECOMMENDATIONS

The results of this annual compliance inspection indicate that the facility's manufacturing operations are being operated in a manner consistent with its operating permits. During the inspection, the facility's permitted equipment appeared to be well maintained and functioning in accordance with all applicable permit limits and operational restrictions.

Record-Keeping and Reporting Discrepancy

During the record-keeping review portion of the inspection, it was discovered that the source does not calculate and report emissions resulting from the combustion of natural gas in the catalytic oxidizer. Natural gas records were produced upon request after the inspection, but the facility's previous emission reports to the Department do not include products of combustion associated with the operation of the catalytic oxidizer. **Follow-Up Action Required: The Department is requiring the source to submit natural gas usage information and associated emission calculations for the calendar years 2014 through 2018 to this office within 30 days of receipt of this report.**

Permit Renewal

Operating permit 00477-02P is set to expire on March 16, 2020. In accordance with Condition V.17. of Appendix A, the facility owner is required to submit an application for permit renewal at least 60 days prior to the expiration date. Please contact this office for any assistance required in completing this submittal.

The source's Ethylene Oxide throughput and emissions for the 2018 calendar year are summarized in the table below:

Facility-Wide
Throughput and Emission Summary

Ethylene Oxide (ton/yr)	Emissions (ton/yr)		Compliance Status (In/Out)
	Allowable	CY2018 Actual	
Throughput	158.78	38.26	IN
Emissions	1.59	0.82	IN

Based on the review of record keeping provided by facility representatives and visual observations made during the physical site inspection, the Department considers the Sterilization Services of Tennessee facility located at 2396 Florida Street in Memphis, TN to be **pending compliance** with their current operating permit. The Department will re-assess this source's compliance status upon receipt of the requested information.

Mark A. Landry
Engineer B

4/1/19
Date